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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,083	03/12/2004	Charles S. Schasteen	NVI 5183.7	8520
321	7590	04/11/2007		
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			EXAMINER FORD, VANESSA L	
			ART UNIT	PAPER NUMBER
			1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary

Application No.

10/799,083

Applicant(s)

SCHASTEEN ET AL.

Examiner

Vanessa L. Ford

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 January 0101.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) 1,7,14-16,19-22 and 27-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6, 8-13, 17-18 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/16/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 3-6 filed on January 16, 2007 is acknowledged. Claims 2, 6, 8, 17 and 24-26 have been amended. Claims 1, 7, 14-16, 19-22 and 27-101 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 2-6, 8-13, 17-18 and 23-26 are under examination.

The traversal is on the grounds that Groups I-VIII are not independent and distinct, therefore the examination of the entire application does not constitute a serious burden.

These arguments have been fully considered but are not found to be persuasive for the reasons below:

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct patented inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related as methods of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.01). In the instant situation, the inventions of Groups I-VIII are drawn to distinct inventions which are

Art Unit: 1645

methods capable of separate manufacture, use or sale as described in the previous Office Action.

Classification of the subject matter is merely one indication of the burdensome nature of the search. The literature search, particularly relevant in this art, is not co-extensive, because for example, Groups I-VI and VIII is drawn to distinct methods and Group VII is drawn to products. Specifically, different separation techniques such as the use of hydrocyclones or centrifugation required different method steps and reagents. Clearly different searches and issues are involved in the examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Specification

2. The use of the trademarks have been noted in this application. See for example, pages 28 or 45. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. The specification should be reviewed for these types of informalities and correction is required.

3. The specification is objected to for the following informality: the reference to the article in *Parasitology* 73:311-326 should be "Ryley" et al instead of "Ryler et al." See page 17. The specification should be reviewed for these types of informalities and correction is required.

4. The specification is objected to for the following informality: the specification recites "4□ C" . See page 34. It is unclear what Applicant intends. Does Applicant intend "4°C". The specification should be reviewed for these types of informalities and correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 9 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites "...relative proportions...". It is unclear as to what Applicant is referring. It is unclear as to whether Applicant intends. Clarification/correction is required.

6. Claims 5-6 and 17-18 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5-6 and 17-18 recite "... centrifugal -based separation ...". It is unclear as to what Applicant is referring. It is unclear as to whether Applicant intends separation of fecal matter by centrifugation or hydrocyclone. Clarification/correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2-6, 8-10, 17-18 and 22-26 are rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al (*WO 00/50072 published August 31, 2000*) in view of Singh et al (*Cereal Chemistry, 72(4):344-348, 1995*).

Claims are drawn to a method of separating or isolating oocysts from a liquid suspension by the use of a hydrocyclone.

Conkle et al teach methods of isolating and separating oocysts from *Eimeria* species (oocysts known to cause coccidiosis) (see the Abstract). Conkle et al teach that encysted protozoa (oocysts) are obtained from feces, the suspensions or slurries

Art Unit: 1645

can include significant amounts of undesirable suspended solids (pages 4-5). Conkle et al teach that the encysted protozoa require centrifugation and concentration of the protozoa (page 6). Conkle et al teach that the suspensions can include from about 1 up to about 20 weight percent solid or feces (page 5). Conkle et al teach that the separation methods of the invention include dense salt solutions including water and sodium chloride (page 5). Conkle et al teach that encysted protozoa need to be separated from suspension to achieved at least 70% encysted protozoa recovery (page 5). Conkle et al teach that encysted protozoa can be recovered or separated by salt flotation or gas flotation (page 5). Conkle et al teach that using salt flotation results in about 80 to 95 percent recovery (page 5). Conkle et al teach that the use of gas flotation results in about 20 to 90 percent recovery of encysted protozoa (page 7). However, Conkle et al teach that that gas flotation process rejects about 20 to 90 percent of encysted protozoa (page 7). Conkle et al teach that a need exists for a more efficient vaccination method (page 2). Conkle et al teach that this need would use other techniques to eliminate hazardous chemical such as potassium dichromate in processing the protozoa included in compositions used to vaccinate animals (page 2). Conkle et al teach that the methods of the invention are used to produce vaccines against avian coccidiosis (see the Abstract). Thus, Conkle et al teach the claim limitation that the host animals are from the class Aves.

Conkle et al do not teach hydrocyclones.

Singh et al teach a method of using hydrocyclones in separation processes (see the Abstract). Singh et al teach disclosed the use off the Doxie Type A single

Art Unit: 1645

hydrocyclone (see the Abstract). Singh et al teach using hydrocyclones in separation processes increased the yield of product (see the Abstract). Singh et al also teach that using hydrocyclones reduced the amount of time of the separation process (see the Abstract). Singh et al teach that hydrocyclones eliminated the requirement of a large floor area, reduced the potential for error and more closely simulated the separation processes used in industrial operations (see the Abstract). Claim limitations such as density and appearance of the oocysts would be necessarily taught by the prior art references since oocysts are encysted from *Eimera*. Claim limitations such as specific density ranges would be a matter of optimizing experimental parameters.

It would be *prima facie* obvious at the time the invention was made to modify the separation and isolation procedures as taught by Conkle et al to use hydrocyclones because Singh et al teach using hydrocyclones in separation processes increased the yield of product, reduced the amount of time of the separation process and eliminated the requirement of a large floor area. It would be expected absent evidence to the contrary that the use of hydrocyclones in a method of isolating and separating encysted protozoa (oocysts from *Eimera*) would be effective at reducing the potential for error and more closely simulated the separation processes used in industrial operations.

8. Claims 11-13 are rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al and Singh et al as applied to claims 2-6, 8-10, 17-18 and 22-26 and further in view of Sjoerdsma et al (*U.S. Patent No. 4,399, 151 published August 16, 1983*).

Art Unit: 1645

The teachings of Conkle et al and Singh et al have been described previously. Conkle et al and Singh et al et al do not teach the use of screens.

Sjoerdsma et al teach that mesh screens can be used to extract debris from biological material (Example 6, column 24).

It would have been *prima facie* obvious at the time the invention was made to include a mesh screen in the method of Conkle et al and Singh et al as combined above because demonstrate that mesh screens are effective at separating debris or contaminants from biological material. It would be expected that using mesh screens would be an effective way to eliminate contamination from oocysts.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Vanessa L. Ford
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March 31, 2007



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